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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,170	04/09/2004	Akihiko Chiba	108421-00096	8399

4372 7590 07/30/2010

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ART UNIT	PAPER NUMBER
1793	

NOTIFICATION DATE	DELIVERY MODE
07/30/2010	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte AKIHIKO CHIBA, YOSHIKI ONO,
SHIGEMI SATO, MICHIHIKO AYADA, TAKESHI SUZUKI,
MORIMICHI KAI and MASASHI SAKAMOTO

Appeal 2009-006935
Application 10/821,170
Technology Center 1700

Before TERRY J. OWENS, TONI R. SCHEINER, and MARK NAGUMO, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1-4, 11-16, and 23-26,[2] directed to a nickel-free fine wire of a cobalt-chromium-molybdenum alloy. The claims have been rejected as failing to comply with the written description requirement and as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

STATEMENT OF THE CASE

The present invention is directed to a nickel-free fine wire of a cobalt-chromium-molybdenum alloy "having excellent biocompatibility, corrosion resistance, wear resistance, processability, flexibility" and a "high degree of roundness" (Spec. ¶¶ 1, 10).

Claim 1 is representative of the claimed subject matter:

1. A Co-Cr-Mo alloy fine wire for biomaterials, consisting of: 26 to 31 weight % of Cr; more than 8 weight % to 16 weight % of Mo; and the remainder of Co and inevitable impurities, the alloy being Ni-free; the wire having a diameter of 200 micrometers or less and a degree of roundness (minor diameter/major diameter) of lateral cross section of 0.6 or more, and a uniform structure with a concentration ratio of maximum Mo concentration phase with respect to minimum Mo concentration phase of 1.8 or less when Mo concentration is measured at one or more arbitrarily selected cross sections of said fine wire,

wherein the wire was obtained by injecting the melted Co-Cr-Mo alloy from a nozzle to form a melted alloy jet and cooling and solidifying the melted alloy jet.

The Examiner rejected the claims as follows:

- Claims 1-4, 11-16, and 23-26 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.

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[2] Claims 5-10 and 17-22 are also pending, but have been withdrawn from consideration (App. Br. 2).

- Claims 1-4, 11-16, and 23-26 under 35 U.S.C. § 103(a) as unpatentable over Stinson (U.S. Patent 5,891,191, issued April 6, 1999).

- Claims 1-4, 11-16, and 23-26 under 35 U.S.C. § 103(a) as unpatentable over Stinson in view of Chiba[3] (JP 2002363675, published December 18, 2002).

WRITTEN DESCRIPTION

Issue

The Examiner finds that "the recitation 'the alloy being Ni-free'" is new matter because "there is not a recitation of the alloy being 'Ni-free' in the 'SUMMARY OF THE INVENTION' section or the 'EXAMPLES' section of the instant specification" (Ans. 4).

Appellants contend that "the Specification does provide sufficient support for the feature of the alloy being nickel-free" (App. Br. 8), at least in part because the Specification teaches that the alloy of the invention has "excellent biocompatibility," and also teaches that nickel is allergenic, thus, "it is 'preferred not to contain nickel in fine-wire used in the medical field'" (*id.*).

The issue raised by this rejection is whether Appellants' disclosure, as originally filed, conveys with reasonable clarity to those skilled in the art that Appellants were in possession of a nickel-free fine wire of Cr-Co-Mo alloy.

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[3] The Examiner refers to this reference as Masahiko.

Findings of Fact

Under the heading "Background of the Invention" and the sub-headings "Field of the Invention" and "Related Art," the Specification indicates that alloys of cobalt, chromium, and molybdenum were known to be biocompatible, but unsuitable for processing into fine wire for use in prosthetic materials because of poor "plastic processability" (Spec. ¶¶ 1, 2).

According to this portion of the Specification, the prior art met the "keen demand for development of fine wire made of this alloy having strength, wear resistance, and torsional rigidity conforming to dynamic[s] characteristic of biomaterials, and flexibility" (*id.* at ¶ 2) "by manufacturing a long member of Co-Cr-Mo containing Ni by less than 5 weight %" (*id.* at ¶ 3), and by "increasing the Mo concentration and homogenizing the structure" (*id.* at ¶ 4).

The increased molybdenum concentration of the prior art alloy was said to improve the alloy's corrosion resistance and wear resistance at the expense of plastic workability (*id.* at ¶ 4), while the inclusion of nickel was said to impart increased flexibility and plastic workability (*id.* at ¶ 3).

However, the Specification also indicates that "Ni is allergenic, and it is preferred not to contain Ni in fine wire used in the medical field" (*id.* at ¶ 3). Thus, according to the Specification, "there has been a strong demand for development of Ni-free fine wire with Mo content of 8 weight % or more, which is superior in corrosion resistance, wear resistance, and flexibility" (*id.* at ¶ 6), and "it has [also] been desired to develop . . . a fine wire having a high degree of roundness" (*id.* at ¶ 7).

Under the subsequent heading "Summary of the Invention," the Specification states that:

> The invention was made in light of the above demands, and it is hence an object thereof to present a Co-Cr-Mo alloy fine wire capable of assuring the original excellent biocompatibility of Co-Cr-Mo alloy fine wire, exhibiting superior corrosion resistance, wear resistance, and processability, and excellent in fitting to shape of biomaterial[.]

(*Id.* at ¶ 8.)

According to the Specification, the Co-Cr-Mo alloy fine wire of the invention exhibits "excellent corrosion resistance, wear resistance and processability" "while maintaining the original excellent feature of biocompatibility" (Spec. ¶ 15). This is accomplished, at least in part, by optimizing the molybdenum and chromium concentrations, and melt spinning the molten alloy into rotating fluid or gas (*id.* at ¶ 10), thereby avoiding "high Mo concentration phases and low phases" and "making the Mo concentration uniform" (*id.* at ¶ 11). "[T]hat is, by optimizing the concentration ratio of Mo concentration low phases and Mo concentration high phases, it is . . . possible to obtain fine wires which are excellent in ductility and also in processability" (*id.*).

Finally, Tables 1 and 2 of the Specification show the results of measuring the blending composition and the molybdenum concentration of fine wire fabricated according to the invention at various positions along the wire. In all cases, the weight percents of cobalt, chromium, and molybdenum add up to 100% (Spec. ¶¶ 50-53).

Discussion

"In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue." *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). Rather, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. *See id.*

We agree with Appellants that the Specification as filed provides adequate written descriptive support for a nickel-free fine wire of Co-Cr-Mo alloy, despite the lack of a recitation *in haec verba*, given the Specification's teaching that nickel is problematic in medical applications because of its allergenicity; the assertion that the fine wire of the invention exhibits "superior corrosion resistance, wear resistance, and processability," *as well as* "excellent biocompatibility" (Spec. ¶ 8), and the fact that Tables 1 and 2 of the Specification show that the weight percentages of cobalt, chromium, and molybdenum in the fine wire of the invention total 100%.

Conclusions of Law

Appellants' disclosure, as originally filed, conveys with reasonable clarity to those skilled in the art that Appellants were in possession of a nickel-free fine wire of a Cr-Co-Mo alloy.

OBVIOUSNESS

Issue

The Examiner finds that Stinson "teaches a cobalt-chromium-molybdenum alloy fine wire . . . for an implantable device . . . comprising (in weight percent): 26-31% chromium, 4-8% molybdenum, <2% nickel, [with the] balance cobalt" (Ans. 5), and also teaches that nickel enhances the

ductility of the wire (*id.* at 12). The Examiner cites Chiba as teaching that a higher proportion of molybdenum than the 4-8 weight percent disclosed by Stinson is "useful for improving corrosion and abrasion resistance" (Ans. 8).

Appellants contend that "a rational understanding" of Stinson is that nickel is present in Stinson's alloy, and the reference "fails to disclose or suggest an alloy that is nickel-free" (App. Br. 10).

The Examiner's response, on the one hand, is that "'less than about 2 weight percent nickel' would encompass 0 weight percent nickel" (Ans. 12), and on the other hand, that "it would have been obvious . . . to omit nickel where improved ductility would not be required or desired" (*id.*).

The interrelated issues raised by the rejections of claims 1-4, 11-16, and 23-26 as unpatentable over Stinson, and also as unpatentable over Stinson in view of Chiba, are the same:

Can Stinson reasonably be interpreted as disclosing a fine wire fabricated from a completely nickel-free Co-Cr-Mo alloy? If not, would one of skill in the art have had a reason to eliminate nickel from Stinson's alloy altogether?

Findings of Fact

Stinson describes various commercially available cobalt-based alloys which also include chromium, iron, molybdenum, and 10-20% nickel (Stinson, col. 1, l. 44 to col. 2, l. 6). According to Stinson, "[n]ickel enhances the ductility of the alloys, improving its ability to be mechanically drawn or formed . . . into wire of the relatively fine diameters required for stents . . . by a process known as cold working" (*id.* at col. 2, ll. 4-9). The drawn wire is subsequently heat treated to improve its yield strength (*id.* at col. 2, ll. 15-19).

Stinson teaches that chromium-cobalt-molybdenum alloys with "relatively low nickel content (about 1% maximum)" are "highly biocompatible" (*id.* at col. 3, ll. 15-17), but "conventional wisdom has been that these alloys cannot be cold drawn down to the fine wire diameters needed for stents" because their "relatively low ductilities and high work hardening rates . . . limit their formability" (*id.* at col. 3, ll. 18-22).

Stinson explains that his invention "is based on the discovery that contrary to conventional wisdom, certain cobalt-chromium-molybdenum (Co-Cr-Mo) alloys containing less than about five weight percent nickel can be drawn or otherwise formed by cold working into wrought elements such as filaments . . . suitable for stents" (*id.* at col. 4, ll. 11-22), even without subsequent heat treating (*id.* at col. 6, ll. 30-32). Stinson specifies that the filaments are preferably formed from alloys "containing less than about two-weight percent nickel, and more preferably containing no more than about one weight percent nickel" (*id.* at col. 5, ll. 23-25).

Finally, Stinson describes the properties of "[s]ample filaments . . . cold drawn from BioDur Carpenter CCM® alloy . . . The published composition of this alloy is Co, 26 Cr, 6 Mo, 1 Si, 1 Fe, 1 Mn, *1 Ni*, 0.5 W, 0.5 Cu, 0.18 N, 0.05 C, 0.015 P, 0.015 S"[4] (*id.* at col. 5, ll. 52-57; emphasis added). Stinson compares the physical properties of the finished wire to those of wires made of cold worked, heat treated alloys of similar diameter,

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[4] The position of the commas makes this excerpt somewhat confusing, because the percentage of cobalt is not given directly in the list - cobalt makes up the difference after all the other components are totaled, and is preferably at least 60.0 weight percent (Stinson, col. 5, ll. 43-45). Thus, according to Stinson, the published nickel content of BioDur Carpenter CCM® alloy is 1% by weight, making the cobalt content 63.64% by weight.

but higher nickel content, and concludes "[e]quivalent physical stent characteristics can . . . be obtained from a stent that has a relatively low nickel content . . . solely by cold working the alloy" (*id.* at col. 6, ll. 28-32).

Discussion

Stinson teaches that the inclusion of ten to twenty percent nickel in cobalt-chromium-molybdenum alloys was known to improve the ductility of the alloys to the point where they could be formed into wires of relatively fine diameters by cold working. Stinson's contribution to the art is the recognition that, "contrary to popular wisdom," alloys with less than five percent nickel—even as little as 1 percent—could be drawn into fine wire by cold working—and with physical properties comparable to alloys with higher amounts of nickel.

While it's true that a reference's disclosure isn't limited to its working examples, that doesn't mean that the examples can't inform the scope of the disclosure. In this case, Stinson doesn't discuss making fine wires by cold working alloys completely devoid of nickel, not even for the sake of comparison with nickel-containing wire. We agree with Appellants that one of skill in the art would not reasonably interpret Stinson as disclosing an alloy completely devoid of nickel, despite the lack of a discrete lower limit on the range given for nickel in Stinson's alloy.

That being said, it may well be, as the Examiner alternatively argues, that "it would have been obvious . . . to omit nickel where improved ductility would not be required or desired" (Ans. 12). The problem with this rationale is that the claims are directed to "a Co-Cr-Mo fine wire for biomaterials," which the record establishes *does* require ductility and plastic workability. The Examiner has failed to come forward with any credible evidence that

the prior art relied on to reject the claims provided any method of obtaining alloys for wires having ductility and plastic workability in the absence of nickel, or even with substantially less than 1% Ni.

Conclusions

Stinson cannot reasonably be interpreted as disclosing a fine wire fabricated from a completely nickel-free Co-Cr-Mo alloy. Moreover, the Examiner has not established that one skilled in the art would have been led to eliminate nickel from Stinson's alloy altogether when drawing fine wire from the alloy.

We conclude that the Examiner failed to prove a prima facie case of obviousness.

SUMMARY

- The rejection of claims 1-4, 11-16, and 23-26 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement is reversed.

- The rejection of claims 1-4, 11-16, and 23-26 under 35 U.S.C. § 103(a) as unpatentable over Stinson is reversed.

- The rejection of claims 1-4, 11-16, and 23-26 under 35 U.S.C. § 103(a) as unpatentable over Stinson in view of Chiba is reversed.

REVERSED

alw

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